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Guy E. Beardsley

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ausubel et al. Art Unit: 1645

Serial No.: 08/962,750 Examiner: R. P. Swartz

Filed: November 3, 1997 Customer No.: 21559

Title: METHODS OF SCREENING COMPOUNDS USEFUL FOR
PREVENTION OF INFECTION OR PATHOGENICITY

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PETITION FROM REFUSAL TO ADMIT AMENDMENT
UNDER 37 C.F.R. §§ 1.127 and 1.181

Applicants respectfully request, under 37 C.F.R. §§ 1.127 and 1.181, entry into the record of their Supplemental Amendment mailed October 16, 2000.

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AND INTERFERENCES

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Background

In its final Office Action issued October 14, 1999, the Office, remarking on the sole remaining issue of obviousness in this case, stated:

The examiner has considered applicants' arguments, but does not find them persuasive. The instant claims are direct[ed] to a method of identifying compounds which inhibits or reduces pathogenicity of the same pathogen in at least two different eukaryotic organisms, one of which is a non-rodent. The claims are not directed to identifying common or different virulence factors, therefore applicants' argument concerning recognition of whether the pathogenicity in plants and animals is due to common or different virulence factors is directed to a criticality not claimed. (emphases original.)

On April 14, 2000, applicants, in response to the final Office Action, amended their claims.¹ In their remarks accompanying this amendment, applicants stated:

The sole issue remaining in this case concerns the obviousness of claims 1-24, 26, and 28-30 in view of several references presently made of record in this case. While not conceding that the claims as filed are obvious over these references, in the interest of expediting prosecution, the present amendment more closely focuses the claimed invention on the "common virulence factor" concept, which the Examiner believes is a concept not presently claimed. As amended, the claims are now directed to cover applicants' technical breakthrough demonstrating the existence of common virulence factors that are used by pathogens to infect multiple hosts, which is nowhere taught or suggested by the references of record in this case. The § 103 rejection can now be withdrawn.

¹ Copies of applicants' Appendix B: Claims on Appeal (As Amended by Supplemental Amendment) and Supplemental Amendment, each mailed October 16, 2000, are enclosed. This amendment, which, with respect to claims 1 and 22, is identical to that submitted by applicants with their reply of April 14, 2000.

In its advisory action, the Office stated:

[T]he amendment raises the issues of how to distinguish between compounds which inhibit or reduce pathogenicity by affecting the function of a common virulence factor versus affecting the function of a multiple virulence factors. There are no method steps for making such distinction.

In addressing the Office's statement in the Advisory Action, Applicants, in their Appeal Briefs dated October 16, 2000 and February 15, 2001, again requested entry of its Supplemental Amendment, stating:

[A]ppellants respectfully request entry of the Supplemental Amendment mailed concurrently with this appeal. This amendment, which, with respect to claims 1 and 22, is identical to that submitted by appellants with their reply of April 14, 2000, narrows the issues on appeal and expedites resolution of this case. This amendment raises no issues requiring a new search, as the Office's initial search is believed to have covered the common virulence factor concept embodied in appellants' claims as originally filed and as disclosed in appellants' specification. (See, for example, appellants' specification, at page 3, under the heading "Summary of Invention," where it is stated: "We have discovered that common pathogenic virulence factors are involved in infection and pathogenicity of both animal and plant hosts.") Similarly, the amendment does not raise any issue relating to the addition of new matter.

With respect to the statement made in the Advisory Action that there are no method steps for distinguishing between compounds which inhibit or reduce pathogenicity by affecting the function of a common virulence factor (versus affecting the function of multiple virulence factors), appellants respectfully point out that the amended claims do make this distinction. In particular, paragraph (b) of amended claims 1 and 22 requires identifying a compound that inhibits or reduces pathogenicity of the same pathogen in the two different hosts as a consequence of affecting the function of said common virulence factor in said same pathogen. Accordingly, it is appellants' position that this amendment does no more than

narrow the issues on appeal, and on this basis request its entry.
(emphasis original.)

In its "Remand To The Examiner," the Board of Patent Appeals and Interferences stated:

The examiner did not mention the amendment in the Examiner's Answer. In their Reply Brief, Appellants again repeated their request for entry of the amendment. See Paper No. 24, filed November 12. 2002, pages 4 and 5-6. The examiner responded simply that the Reply Brief had been entered and considered. See Paper No. 25, mailed January 15. 2003.

The record does not make clear whether the examiner has entered Appellants' amendment. On one hand, the examiner did not expressly state that the amendment would be entered, either in the Examiner's Answer or in the response to the Reply Brief. This might be taken to mean the amendment was denied entry sub silentio, since an amendment after final rejection is not entered as a matter of right. See 37 C.F.R. § 1.116.

On the other hand, in responding to Appellants' arguments, the examiner state that "[t]he claims...state a description of the pathogen as "said same pathogen utilizing a common virulence factor to infect said eukaryotic organisms' and that a compound's inhibition or reduction of pathogenicity is 'a consequence of affecting the function of said common virulence factor in said pathogen." Examiner's Answer, page 7. The limitations quoted by the examiner are those that were requested in the amendment. Thus, this passage from the Examiner's Answer suggests that the examiner intended to enter the amendment.

Our review of the appealed rejection may be affected by the entry (or non-entry) of the amendment. The test of obviousness is whether the claimed "subject matter as a whole would have been obvious" in view of the prior art. 35 U.S.C. § 103. "The Patent and Trademark Office (PTO) must consider all claim limitations when determining patentability of an invention over the prior art." *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994). The additional limitations requested by Appellants in their Supplemental Amendment change the scope of the claimed method of and

may change whether those skilled in the art would have found it obvious in view of the cited references.

On return of this application, the examiner should clarify whether or not Appellants' amendment filed October 16, 2000 (Paper No. 20), has been entered. Entry of an amendment filed after a notice of appeal is not a matter of right, and the examiner should consider whether the proposed amendment complies with 37 C.F.R. § 1.116. See Manual of Patent Examining Procedure § 1207. If the examiner refuses to enter the proposed amendment, and Appellants seek review of that decision, review must be had by way of petition, not appeal. See 37 C.F.R. § 1.127.

In an Office Communication dated January 20, 2004, the Office, in its response to the Board's "Remand To The Examiner," stated:

4. The examiner confirms the Board's reasoning that the proposed amendments to the claims, which were part of the Appeal Brief, were denied entry sub silentio because of the same recurring new matter issues. The Examiner's Answer is based upon the claim language which was of record with the Advisory Action, paper #18, 5/00.

5. The Examiner wishes to clarify for the Board the passage on page 7 of the Examiner's Answer. This argument was based upon Appellants' arguments concerning the proposed, but never entered, new language. The Examiner did not find it persuasive because the claim language on Appeal is the claim language which was of record with the Advisory Action, paper #18, 5/00. This claim language does not contain the criticality that the pathogenicity is due to common or different virulence factors.

Applicants' Amendment Narrows the Issues on Appeal and Should Be Entered Into the Record

Applicants' amendment clearly narrows the issues on appeal and expedites resolution of this case. Moreover, as noted in previous correspondence, this amendment raises no issues requiring a new search, as the Office's initial search is believed to have

covered the common virulence factor concept embodied in applicants' claims as originally filed and as disclosed in applicants' specification. (See, for example, applicants' specification, at page 3, under the heading "Summary of Invention," where it is stated: "We have discovered that common pathogenic virulence factors are involved in infection and pathogenicity of both animal and plant hosts."). Further, applicants respectfully note that that, given applicants' position, the Office has failed to provide a reasonable explanation as to why a new search is required. Applicants further note that the amendment does not raise any issue relating to the addition of new matter. In short, applicants' amendment clearly complies with 37 C.F.R. § 1.116.

Furthermore, with respect to the Office's statement made in the Advisory Action that there are no method steps for distinguishing between compounds which inhibit or reduce pathogenicity by affecting the function of a common virulence factor (versus affecting the function of multiple virulence factors), applicants respectfully point out that the amended claims do make this distinction. In particular, paragraph (b) of amended claims 1 and 22 requires identifying a compound that inhibits or reduces pathogenicity of the same pathogen in the two different hosts as a consequence of affecting the function of said common virulence factor in said same pathogen.

CONCLUSION

Applicants' amendment does no more than narrow the issues on appeal, and on this basis applicants request entry of this amendment.

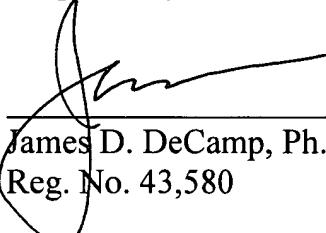
Enclosed is a check in the amount of \$130.00 in payment of the fee required by 37 C.F.R. § 1.17(h).

A courtesy copy of this Petition has been forwarded, by facsimile, to the Board of Patent Appeals and Interferences.

If there are any other charges, or any credits, with respect to this petition, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 22 March 2004



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